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| 10/600,623 | 06/20/2003 | Uri H. Saragovi | 62950-010310 | 7195 |

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| EXAMINER | |
|---|---|
| FETTEROLF, BRANDON J | |
| **ART UNIT** | **PAPER NUMBER** |
| 1642 | |

DATE MAILED: 02/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/600,623 | SARAGOVI ET AL. | |
| | Examiner | Art Unit | |
| | Brandon J. Fetterolf, PhD | 1642 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *14 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *35-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Saragovi et al.

***Response to the Amendment***

The Amendment filed on 11/14/2005 in response to the previous Non-Final Office Action (05/12/2005) is acknowledged and has been entered.

New claims 35-37 are currently pending and under consideration.

**The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.**

**Rejections Maintained**

New claims 35-37 **are/remain** rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, the claims are inclusive of a genus of compounds of the formula W-Z-X which by-pass tumor resistance mediated by p-glycoprotein, wherein X is a chemotherapeutic agent, Z is a breakable linker and W is a targeting moiety, wherein the targeting moiety is a genus of antibodies or a genus of ligands. However, the written description in this case only sets forth on species of a compound of formula W-Z-X which by-pass tumor resistance mediated by p-glycoprotein, wherein X is doxorubicin, Z is a cleavable linker, and W is mAb α-IR3.

The specification teaches (page 4, line 31 to page 5, line 10) that the compounds of the invention include, but are not limited to, compounds represented by the formula W-Z-X, wherein X is a therapeutic agent such as a chemotherapeutic agent or an antiviral agent, Z is a cleavable linker which is breakable by pH modification, reduction or enzymatic hydrolysis and W is a molecule which is adapted to selectively bind the target cell directly or indirectly such as an antibody. Specifically, the specification teaches (page 5, lines 17-22) that chemotherapeutic include not only include taxanes, but also any chemotherapeutic agent such as taxane derivatives, doxorubicin, or daunomycin. In addition, the specification teaches (page 6, lines 11-13) that antibodies of the preferred embodiment include monoclonal antibodies MC192, 5C3 or α-IR3. However, the written

description (specification, page 10, lines 24-33 and page 24, line 16 to page 24, line 24) only reasonably conveys one species of a compound of formula W-Z-X, wherein X is doxorubicin, Z is a cleavable linker, and W is mAb α-IR3, in association with bypassing the p-glycoprotein-mediated resistance. A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or by describing structural features common the genus that "constitute a substantial portion of the genus." See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997): "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cNDA, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus."

The court has since clarified that this standard applies to compounds other than cDNAs. See University of Rochester v. G.D. Searle & Co., Inc., __F.3d__,2004 WL 260813, at *9 (Fed.Cir.Feb. 13, 2004). The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features that are common to the genus. That is, the specification provides neither a representative number of conjugates that encompass the genus of compounds of formula W-Z-X that bypass p-glycoprotein-mediated resistance nor does it provide a description of structural features that are common to the compounds of formula W-Z-X. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the disclosure of one species of compounds which bypass p-glycoprotein mediated resistance is insufficient to describe the genus. Thus, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure(s) of the encompassed genus of compounds, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation.

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence. Therefore, only a compound of formula W-Z-X, wherein X is doxorubicin, Z is a cleavable linker, and W is mAb α-IR3, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

In response to this rejection, Applicants contend that limiting the chemotherapeutic agent X to doxorubicin would be unduly restrictive and unfair to the Applicants, as the specification did have examples for other chemotherapeutic agents such as paclitaxel. For example, Applicants assert that Figures 5 to 7 illustrate the use of paclitaxel, wherein Figure 7 illustrates that paclitaxel-MC192 is efficient at reducing tumor growth and at increasing survival in vivo. Furthermore, Applicants submit that in view of these examples, the person skilled in the art would have no hesitation replacing doxorubicin with other chemotherapeutic agents that could be coupled to a compound defined in new claim 35. With regards to limiting the ligand W to a specific monoclonal antibody such as a-IR3, Applicants argue that the limitation would be unduly restrictive and unfair. For example, Applicants argue that the specification did have examples of other mAbs such as MC192 (p75 binding) and 5C3 (TrkA binding). Moreover, Applicants contend that the application describes compounds in accordance with a preferred embodiment of the present invention, wherein W is a primary biologically active molecule indirectly binding to the target cell, the compound further comprises W' which is a secondary biologically active molecule biding to W and adapted to selectively bind the target cell. In addition, Applicants argue that the application describes a compound in accordance with another embodiment of the present invention, wherein a primary antibody is of a species and secondary antibody is of a different species. Applicants further submit that other embodiments add to the teachings of the invention and include an "all purpose secondary

reagent antibody, that can be used to target any receptor indirectly by of biding to a primary antibody targeting any receptor. Lastly, Applicants assert that small peptidomimetic ligand of the HER2 receptors as ligands coupled to Taxol can be used, wherein these results were obtained from the teachings of the present invention and are reported in the enclosed references: Guillemard et al. DNA and Cell Biology 2005; 24: 350-358 and Guillemard et al. Cancer Research 2001; 61: 694-699.

These arguments have been carefully considered, but are not found persuasive.

In response to Applicants arguments that limiting the chemotherapeutic agent X to doxorubicin would be unduly restrictive because the specification provides examples of other chemotherapeutic agents, the Examiner acknowledges the Examples set for in Figures 5 to 7 and agrees with Applicant with respect to written description for paclitaxel-MC192. However, the Examiner recognizes that the Written Description Guidelines for examination of patent applications indicates, "the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical characteristics and/or other chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show applicant was in possession of the claimed genus." (Federal register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 column 3) and (see MPEP 2164). Thus, while the specification contemplates a genus (see for example page 5, lines 17-22 of the specification) and discloses two species, wherein the species are structurally divergent, the specification does not appear to reasonably convey that they were in the possession of the broad genus of structurally divergent chemotherapeutic agents at the time the invention was made. With regards to Applicants assertion that limiting the ligand W to a specific monoclonal antibody such as αIR3 mAb would be unduly restrictive and unfair because the specification provides other examples such as MC192 and 5C3, the Examiner acknowledges and agrees with Applicants assertion that the specification provides a written description for two additional species. However, as set forth above, the Examiner recognizes that that the Written Description Guidelines for examination of patent applications indicates, "the written description requirement for a claimed genus may be satisfied

through sufficient description of a representative number of species by actual reduction to practice, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical characteristics and/or other chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show applicant was in possession of the claimed genus." (Federal register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 column 3) and (see MPEP 2164). In this situation, the claims encompass a genus of targeting agents selected from a sub-genus of monoclonal antibodies or a sub-genus of ligands, while the specification disclose a species of monoclonal antibodies specific for IGF-IR, p75 receptors and TrkA and appears to be silent on the structural features that are common to the genus of ligands. As such, the specification only reasonably conveys three species of targeting agents, wherein the targeting agents are antibodies to IGF-IR, p75 and TrkA. In response to Applicants contention that the specification describes compounds of the following: W is a primary biologically active molecule indirectly binding to the target cell, the compound further comprises W' which is a secondary biologically active molecule biding to W and adapted to selectively bind the target cell; a primary antibody is of a species and secondary antibody is of a different species; and "all purpose secondary reagent antibody, that can be used to target any receptor indirectly by of biding to a primary antibody targeting any receptor, the Examiner acknowledges that the specification attempts to describe a genus of "compounds" defined solely by its principal biological property. However, the Examiner recognizes that this attempt appears to be simply a wish to know the identity of any material with that biological property. Accordingly, there is insufficient written description encompassing the genus of compounds as described in the speciation because the relevant identifying characteristics of the genus such as structure or other physical and/or chemical characteristics of the genus of "compound" are not set forth in the specification as-filed, commensurate in scope with the claimed invention. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (see page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (see Vas-Cath at page 1116). Lastly, with regards to Applicants submission that a small peptidomimetic ligand of the

HER2 receptor as ligands (W) coupled to Taxol can be used (see for example Guillemard et al. DNA and Cell Biology 2005; 24: 350-358), the Examiner acknowledges the enclosed 2005 reference providing a small peptidomimetic ligand of the HER2 receptor as ligands (W) coupled to Taxol. However, the Examiner recognizes that the question for written description is whether the specification describes in such a way to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention (emphasis added). Thus, while the specification suggests the tumor marker HER2/Neu, the specification appears to be silent on the disclosure of the species as set forth in the enclosed 2005 reference.

Therefore, new claims 35-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

New claims 35-38 **are/remain** rejected under 35 U.S.C. 102(b) as being anticipated by Kopecek et al. (U.S. 5,258,453 1993).

Kopecek et al. disclose a method of minimizing the amount of cancer cells which are resistant to chemotherapy, comprising administering a compound comprising a anticancer drug and a targeting moiety, linked via a copolymeric carrier, wherein the polymeric carrier is susceptible to lysosomal hydrolysis (abstract; column 1, lines 51-64; column 3, lines 30-39). With regards to the targeting moiety, the patent teaches (column 4, lines 10-35) that the targeting moiety is a modified glycoprotein or an antibody specific for a tumor cell. The patent further teaches (column 2, line 67 to column 3 line 9) that the marcomoleucle enters the cell via receptor-mediated pinocytosis. Thus, while Kopecek et al. do not characterize the cancer cells being resistant to chemotherapy as a result of p-glycoprotein, the effect recited in the preamble would be an inherent property of the referenced method since resistance to chemotherapy in cancer cells is mainly mediated by overexpression of p-glycoprotein as evidenced by Dietro et al. (Braz. J. Med. Biol. Res. 1999; 32; 925-939). Moreover, Kopeck et al.'s method step meets the active steps recited in the claims. Thus, it does not appear that the claim language or limitation results in a manipulative difference in the method steps when compared to the prior art disclosure. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001).

Hence, even though the claims are drawn to a mechanism by which the compound treat a patient, the claimed method does not appear to distinguish over the prior art teaching of the same or nearly the same method. The mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 201 USPQ 658 (CCPA 1979). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. In re Baxter Travenol Labs, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145.

In response to this rejection, Applicants contend that Kopecek et al. does not pertain to Multi Drug Resistance (MDR). For example, Applicants submit that the only statements (with no data to support it in the specification) regarding MDR are the following:

-On page 1, lines 51-54: "The present invention minimizes the amount of cancer cells which are resistant to chemotherapy, thus decreasing substantially the possibility of tumor recurrence."

-Applicants assert that this statement indicates that their invention is better suited to kill tumor cells, thus decreasing the possibility of tumor cells recurring in a drug resistant state after drug treatment which is a concept of drug selection pressure. In contrast, Applicants argue that the present invention is different in that the treatment bypasses the PGP causing resistance of tumor cells.

-On page 1, lines 54-59: "This approach has a higher potential in the successful treatment of multidrug resistant cells (MDR) than the presently available therapies. The concentration of drugs in the cell, when this method is used, is increase, even if the transport of the drugs into the cell interior or MDR cell is impaired."

-Applicants contend that the present invention is not claiming a method that bypasses impaired drug transport into the interior of tumor cells expressing MDR. Morever, Applicants assert that the tumor cells tested in the Kopecek patent are not MDR overexpressing.

Applicants further argue that the authors in Kopecek et al. go further to discard targeted delivery into cell and bypassing MDR (the core of the present invention) with the following statement:

-On page 1, line 65 to page 2, line 2: "The polymeric drug will bind to the cell surface receptor/antigen (sic) or MDR cells and may not be internalized. However, after irradiation, the photoactivatable drug will produce singlet oxygen with consequent membrane damage, ultimately resulting in cell death." (emphasis added)

-Applicants point out that it is not possible that a drug can bypass MDR pumps if it is not internalized.

-On page 8, lines 5-12: "An anticancer drug enhances PDT treatment (and vice versa) because long term cure of solid tumors is difficult to achieve with PDT. On the other hand, chemotherapeutic agents have their own share of problems including multidrug resistance and other toxic side effects. The present invention reduces side effects because lower doses of copolymers are required."

-Applicants contend that this statement clearly and unequivocally indicates that there is nothing relating to bypassing MDR pumps. It is simply that the Kopecek patent claims that lower drug doses kill more efficiently, thus reducing the side effects and potentially avoiding the tumors from evolving towards drug resistance. As such, Applicants assert that the avoidance of drug resistance is not related at all with their invention of bypassing MDR, but simply preventing tumors from being selected towards drug resistance because potentially there are less tumor cells surviving their treatment.

Lastly, Applicants submit that claim 35 ahs been amended to specify that the breakable linker is cleaveable in the cell, where as in Kopecek, the linker is broken outside the cells with light.

These arguments have been carefully considered, but are not found persuasive.

In response to Applicant's argument that Kopecek et al. does not pertain to Multi Drug Resistance (MDR), it is noted that the features upon which applicant relies (i.e., Multi Drug Resistance) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In this case, the claims are drawn to a method of

bypassing tumor cell drug resistance mediated by p-glycoprotein pump (PGP) and do not appear to recite that the tumor cell is resistant to multiple drugs. Assuming, *arguendo*, that the claims are drawn to a bypassing multi-drug resistant tumor cells mediated by p-glycoprotein pump, the recitation that Kopecek et al. do not teach MDR will not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). In this case, Kopecek's method steps meet the active steps of the currently claimed invention, i.e. administering a compound having the formula W-Z-X to selectively kill a tumor cell. Moreover, assuming, *arguendo*, that the preamble is given patentable weight. The preamble of the claims, as stated above, are drawn to a mechanism by which the compound bypasses tumor cell resistance mediated by p-glycoprotein pump (PGP). As such, the mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 201 USPQ 658 (CCPA 1979). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. In re Baxter Travenol Labs, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145. In this case, Applicants have not provided any evidence that the macromolecule as taught by Kopecek et al. comprising an anticancer drug linked to a targeting moiety via a polymeric carrier, such as HPMA, which is susceptible to lysosomal hydrolysis would not by-pass tumor cell resistance mediated by p-glycoprotein pump. While the Examiner agrees with Applicants assertion that Kopecek et al. does not explicitly teach by-passing tumor resistance mediated by p-glycoprotein pump, the mechanism of cell entry by the macromolecule via pinocytosis as taught by Kopecek et al (beginning at column 2, line 26 to column 3, line 9) appears to be same as instantly claimed in view of Minko et al. (J. Controlled Release 1998; 54: 223-233). For example, Minko teaches that HPMA copolymer-ADR conjugates avoid Pgp efflux pump by internalization via endocytosis, wherein the conjugates ultimately accumulates in the perinuclear region; and consequently is inaccessible to the energy dependent efflux pump (page 224, 1st column, 1st full paragraph and page 230, 2nd column,

paragraph bridging column 1 and column 2). Thus, it appears that the macromolecules of Kopecek et al. by-pass resistance of tumor cells by the PGP. With regards to Applicants assertion that Kopecek does not teach internalization of the conjugate and/or that the breakable linker is cleavable in the cell, the Examiner recognizes that one aspect of Kopecek's invention involves the extracellular release of a phoactivatable drug. However, the Examiner recognizes that Kopecek et al., as stated above, teach intracellular drug release (column 3, lines 30-39). Specifically, Kopecek et al. provide (column 9, lines 3-33) specific enzyme cleavable linkers which permit site specific release of the anticancer drug in the lysosomal compartment of the cell.

Therefore, new claims 35-38 are/remain rejected under 35 U.S.C. 102(b) as being anticipated by Kopecek et al. (U.S. 5,258,453 1993).

Therefore, NO claim is allowed

**All other rejections and/or objections are withdrawn in view of applicant's amendments and arguments there to.**

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD
Examiner
Art Unit 1642

BF

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER
2/15/06